IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

AMY K. POHL, an individual, Plaintiff, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL INSTITUTES OF HEALTH, and NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES. Defendants.	Civil Action No. _____ **ELECTRONICALLY FILED**

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

For her complaint against Defendants, United States Environmental Protection Agency ("EPA"), United States Department of Health and Human Services ("DHHS"), Centers for Disease Control and Prevention ("CDC"), National Institutes of Health ("NIH"), and National Institute of Environmental Health Sciences ("NIEHS"), Plaintiff Amy K. Pohl avers as follows:

NATURE OF THE ACTION

1. This action is brought under the Administrative Procedure Act ("APA") and the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, to require Defendants to disclose records and research data which were produced and analyzed under grants awarded by EPA and DHHS and which have been used in the adoption of federal regulations that have the force and effect of law. Although the Supreme Court has recognized that disclosure is the dominant objective of FOIA, Defendants have improperly withheld these records and data from Plaintiff for over two years.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action and the parties pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

3. Plaintiff has exhausted her remedies as provided under the APA and FOIA.

4. Venue is proper in this Court pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

PARTIES

5. Plaintiff is a citizen of the United States and resident of this District who, on or about August 9, 2007, requested certain data and records from Defendants pursuant to FOIA.

6. Defendant EPA is an agency of the United States within the meaning of 5 U.S.C. § 552(f). It is also an "awarding agency" within the meaning of, *inter alia*, 2 C.F.R. § 215.36(d)(1).

7. Defendant DHHS is an agency of the United States within the meaning of 5 U.S.C. § 552(f). Defendants CDC, NIEHS and NIH are also agencies within the meaning of 5 U.S.C. § 552(f) and are component entities of DHHS. Defendants DHHS, CDC, NIEHS and NIH are "awarding agencies" within the meaning of, *inter alia*, 2 C.F.R. § 215.36(d)(1) and 45 C.F.R. § 74.36(d)(1).

8. Under 45 C.F.R. § 74.36(d)(1), Defendants are legally required to obtain and produce the data, records and documents that Plaintiff has requested under FOIA.

FACTUAL HISTORY

9. The federal Office of Management and Budget has promulgated the "Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals and Other Non-Profit Organizations," known as "Circular A-110." It was amended by the so-called "Shelby Amendment," effective in early 2000, to impose certain obligations on those who applied for and received federal funds to conduct

scientific research, including that certain data be provided to the agency awarding federal funds upon request and that the agency make those data available to the public.

10. Under the amended version of Circular A-110, which EPA and DHHS have adopted, Defendants and other federal agencies are required to obtain and disclose "research data relating to published research findings produced under an award that was used by the Federal Government in developing an agency action that has the force and effect of law." *See* 45 C.F.R. § 74.36(d)(1); 40 C.F.R. §30.36(d)(1). The public can request such data through FOIA. *Id.*

11. On or about November 9, 2004, EPA announced a general call for information relating to a potential change to the National Ambient Air Quality Standard ("NAAQS") for lead. In December 2005, EPA issued an air criteria document based upon the information gathered. EPA and its advisory committees subsequently produced multiple reports, including draft risk assessments, and held public hearings.

12. A proposed decision was issued on May 1, 2008, and EPA announced the new National Ambient Air Quality Standards for Lead in November of 2008 at Federal Register Volume 73, No. 219 pp. 66963-67062 (Nov. 12, 2008) ("Final Rule").

13. The Final Rule is a federal regulation with the force and effect of law.

14. In reaching the conclusion that the air lead standard should be reduced by 90%, the Final Rule relied on a study published by Bruce Lanphear, *et al.*, *Low level environmental lead exposure and children's intellectual function: an international pooled analysis*, Envt'l Health Persp., Vol. 113:894-899 (2005) ("Lanphear Study"). As the associated criteria document and public docket demonstrate, the Lanphear Study provided the foundation for EPA's evaluation of the risk of lead in the air, in particular the claim that very low levels of lead in children's blood can cause a decrement in IQ at blood lead levels under 10 micrograms per deciliter ("µg/dL") or even 7.5 µg/dL. *See, e.g.*, Final Rule at 66978-66979 (Table 1). The administrative record is replete with correspondence between Dr. Lanphear, his researchers and the EPA with questions and corrections regarding his data. In reaching its decision to set a lower air lead standard, EPA credited Dr. Lanphear's

conclusion that IQ decrements may occur at very low blood lead levels, Final Rule at 67005 (referring to "air-related IQ loss of 2 points" as the standard for the new rule), and used his research to support EPA's decision to adopt the Final Rule and lower the existing air lead standard. *Id.* at 67006 ("The Administrator judges that such a standard would protect, with an adequate margin of safety, the health of children and other at-risk populations against an array of adverse health effects, most notably including neurological effects, particularly neurobehavioral effects and neurocognitive effect, in children. A standard set at this level provides a very significant increase in protection compared to the current standard."). EPA reviewed and relied upon the Lanphear Study and its underlying data in reaching the Final Rule. (*See generally* Final Rule at 66977 (terming the Lanphear Study "the most compelling evidence for Pb effects at blood levels < 10 µg/dL . . . .")).

15. The Lanphear Study was funded by multiple federal grants. In particular, DHHS grant ES010868 funded, in part, the conference at which the Lanphear Study was proposed and described. In addition, the gathering, analysis and publication of the data that comprised the Lanphear Study occurred under the auspices of the "Center for the Study of Prevalent Neurotoxicants in Children," a multi-million dollar federally-funded project at the University of Cincinnati, jointly funded by the EPA pursuant to grant R829389 and DHHS pursuant to grant ES011261. Progress reports under these grants filed by Dr. Lanphear and colleagues make clear that federal funding produced the Lanphear Study. Moreover, the Lanphear Study itself, published in the 2005 edition of Environmental Health Perspectives, states "[t]his study was funded, in part, by the National Institution of Environmental Health Sciences, the Centers for Disease Control and Prevention, and the U.S. Environmental Protection Agency." All grants were awarded after the effective date of the Shelby Amendment.

PROCEDURAL HISTORY

16. On or about August 9, 2007, Plaintiff sent a letter, attached as Exhibit A hereto, to EPA requesting certain data, data collection forms, software programs necessary to review the data and data dictionaries for the Lanphear Study ("Requested Data").

17. EPA denied Plaintiff's initial request, and Plaintiff filed a timely appeal. On February 14, 2008, EPA's FOIA appeal officer determined that the Requested Data were disclosable under both FOIA and 40 C.F.R. § 30.36, and granted Plaintiff's appeal. A copy of that decision is attached hereto as Exhibit B.

18. In violation of FOIA and the Shelby Amendment, both of which require the responsive agency to obtain and turn over Requested Data, EPA forwarded to the request to DHHS on or about May 29, 2008 ostensibly "for processing."

19. Subsequently, two separate DHHS agencies, CDC (on June 17, 2008) and NIH (on July 1, 2008) acknowledged the transfer from EPA.

20. On October 6, 2008, CDC advised Plaintiff that it was "negotiating the availability of the data and the cost of providing it with the grantee."

21. On December 16, 2008, CDC advised Plaintiff that it had reconsidered her request and would not provide the Requested Data, claiming that the Requested Data were exempt from disclosure under 45 C.F.R. § 74.36(d)(2)(i)(A). A copy of that letter is attached hereto as Exhibit C. This decision effectively overturned the EPA's final appeal decision that the Requested Data were to be produced to Plaintiff.

22. CDC's stated basis for non-production does not apply to these Requested Data as the cited section is inapplicable to Plaintiff's request. The data at issue are not commercial or trade secrets nor does there exist another law that would render the data non-disclosable.

23. On December 18, 2008, NIH (apparently acting independently of CDC) advised Plaintiff that it, too, had reconsidered her request and that it, too, would deny her request, not for the reasons stated by CDC but rather because the NIEHS grants were not sufficiently related to the data or study at issue to be disclosable under applicable federal regulations. A copy of that letter is attached hereto as Exhibit D.

24. NIH's stated reason for non-production does not apply to Plaintiff's request because, as detailed *supra*, the Requested Data were produced and analyzed pursuant to three

separate federal grants, DHHS grant ES010868, EPA grant R829389 and DHHS grant ES011261.

25. Plaintiff filed a timely appeal of both decisions to DHHS by way of a January 9, 2009 letter (attached hereto as Exhibit E).

26. Despite the requirement that the appeal be resolved within twenty days pursuant to 45 C.F.R. § 35(b)(2), DHHS has yet to act on the appeal. Moreover, DHHS has not responded to multiple written inquiries about the status of the appeal.

FIRST CAUSE OF ACTION

Violation of FOIA and the Shelby Amendment
(5 U.S.C. § 552(a)(3); 5 U.S.C. § 552 (a)(4)(B);
2 C.F.R. § 215.36; 45 C.F.R. § 74.36; 40 C.F.R. § 30.36)

27. Paragraphs 1-26 are incorporated herein by reference.

28. Pursuant to FOIA, 5 U.S.C. § 552, and OMB Circular A-110, the terms of which have been codified at 2 C.F.R. § 215.36, 45 C.F.R. § 74.36 and 40 C.F.R. § 30.36, Plaintiff made her initial FOIA request to EPA by letter dated August 9, 2007.

29. The Requested Data were produced under a federal award and were relied upon by EPA in producing a regulation, the Final Rule, that has the force and effect of law.

30. For over two years, Defendants have refused to obtain and produce the Requested Data.

31. Defendants are required by law to obtain and produce the Requested Data to Plaintiff.

32. Defendants have violated, *inter alia,* 5 U.S.C. § 552(a)(3); 5 U.S.C. § 552 (a)(4)(B); 2 C.F.R. § 215.36; 45 C.F.R. § 74.36; 40 C.F.R. § 30.36 by failing to produce to Plaintiff the Requested Data.

33. Plaintiff has exhausted her administrative remedies.

34. Plaintiff has been injured by being denied access to the Requested Data to which she is entitled.

SECOND CAUSE OF ACTION

Violation of FOIA and APA (5 U.S.C. § 552, 702, 705)

35. Paragraphs 1-34 are incorporated herein by reference.

36. FOIA, and its implementing regulations, provide a process by which requests for the production of information, documents and data are made. FOIA governs the production of data disclosable under Circular A-110 as adopted by the various agencies.

37. Section 552 of FOIA provides the process by which initial requests are considered and appeals of adverse determinations are made. In particular, Section 552(a)(6) provides a mechanism by which appeals of denials are considered and finally decided. FOIA provides no mechanism by which one agency may decide an appeal granting access to records or data and then may transfer that request for reexamination and denial by another agency.

38. Defendants violated Section 552 and acted in an arbitrary and capricious manner and in a manner otherwise contrary to law by deciding Plaintiff's appeal and subsequently permitting other FOIA officers at other agencies to re-examine Plaintiff's request and, effectively, permitting those individual FOIA officers to reconsider and reverse the decision of EPA to grant the appeal.

39. Plaintiff has exhausted her administrative remedies.

40. Plaintiff has been injured by being denied the process under FOIA and the APA to which she is entitled.

PRAYER FOR RELIEF

WHEREFORE, and in consideration of the allegations in paragraphs 1-40, Plaintiff hereby requests:

A. An order declaring that Plaintiff is entitled to the Requested Data and other materials requested and granted by way of the EPA decision of appeal;

B. An order compelling Defendants to obtain and turn over to Plaintiff copies of the Requested Data;

C. An order declaring Defendants' actions to be in violation of FOIA and APA;

D. Reasonable attorneys' fees;

E. Costs of suit;

F. Such other relief as the Court deems proper.

Respectfully Submitted,

/s/ Paul J. Jalsevac
Attorney for Plaintiff

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